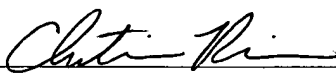


IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of Lowman et al. Serial No.: not yet assigned Filed: Herewith	Group Art Unit: 1644 Examiner: not yet assigned Confirmation No: not yet assigned CUSTOMER NO: 09157
For: Method for Treating IgE-Mediated Disorders (as amended)	<p style="text-align: center;">CERTIFICATION UNDER 37 CFR 1.10</p> <p><u>EV 351928438 US</u> : Express Mail Number <u>March 2</u>, 2004: Date of Deposit</p> <p>I hereby certify that this correspondence is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Commissioner for Patents, Mail Stop Patent Application, P.O. Box 1450, Alexandria, VA 22313-1450</p> <p style="text-align: center;"> Christine Ricks</p>

INFORMATION DISCLOSURE STATEMENT

Mail Stop PATENT APPLICATION
 Commissioner for Patents
 P.O. Box 1450
 Alexandria, VA 22313-1450

Sir:

Applicants submit herewith patents, publications or other information listed on the attached revised Form PTO-1449, of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR §1.56.

This Information Disclosure Statement is filed in accordance with the provisions of:

☒ **37 CFR §1.97(b)**

- within three months of the filing date of the application other than a continued prosecution application under 37 CFR §1.53(d); **or**
- within three months of the date of entry of the national stage of a PCT application as set forth in 37 CFR §1.491, **or**
- before the mailing of the first Office action on the merits; **or**
- before the mailing of the first Office action after the filing of a request for a continued examination under 37 CFR §1.114.

☐ **37 CFR §1.97(c)**

- by the applicant after the period specified in 37 CFR §1.97(b), but prior to the mailing date of any of a final action under 37 CFR §1.113, or a notice of allowance under 37 CFR §1.311, or an action that otherwise closes prosecution in the application, and is accompanied by either the fee set forth in 37 CFR §1.17(p) or a statement as specified in 37 CFR §1.97(e), as checked below.

☐ **37 CFR §1.97(d)**

- after the period specified in CFR §1.97(c), and is accompanied by the fee set forth in 37 CFR §1.17(p) **and** a statement as specified in 37 CFR §1.97(e), as checked below.

[If either of boxes 37 CFR §1.97(c) or 37 CFR §1.97(d) is checked above, the following statement under 37 CFR §1.97(e) may need to be completed.]

- ☐ **37 CFR §1.97(e)** Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement.
- ☐ **37 CFR §1.704(d)** Each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and the communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of this information disclosure statement. Therefore, in accordance with the provisions of 37 CFR §1.704(d), the filing of this information disclosure statement will not be considered a failure to engage in reasonable efforts to conclude prosecution under 37 CFR §1.704.
- ☐ The U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$180.00 to cover the cost of this Information Disclosure Statement under 37 CFR §1.17(p). Any deficiency or overpayment should be charged or credited to this deposit account.

A list of the patent(s) or publication(s) is set forth on the attached revised Form PTO-1449 (Modified).

Those patent(s) or publication(s) which are marked with one asterisk (*) in the attached PTO-1449 form are not supplied because they were previously cited by or submitted to the Office in a prior application Serial No. 09/716,028, filed November 17, 2000 and relied upon in this application for an earlier filing date under 35 USC §120.

Those patent(s) or publication(s) which are marked with two asterisks (**) in the attached PTO-1449 form are not supplied because pursuant to a Patent Office waiver signed July 11, 2003, applicants are no longer required to submit copies of United States patents cited in Information Disclosure Statements for

Serial No.: not yet assigned
Filing Date: Herewith

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applications filed after June 30, 2003 (1276 OG 55).

A concise explanation of relevance of the items listed on PTO-1449 is:

☒ not given

☐ given for each listed item

☐ given for only non-English language listed item(s) [Required]

☐ in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references.

In accordance with 37 CFR §1.97(g), the filing of this information disclosure statement shall not be construed as a representation that a search has been made.

In accordance with 37 CFR §1.97(h), the filing of this information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in 37 CFR § 1.56(b).

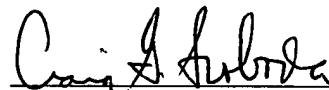
The Commissioner is hereby authorized to charge any additional fees required under 37 CFR 1.16 and 1.17 for this Information Disclosure Statement, or credit overpayment to Deposit Account No. 07-0630.

Respectfully submitted,

GENENTECH, INC.

Date: March 2, 2004

By:



Craig G. Svoboda

Reg. No. 39,044

Telephone No. (650) 225-1489

FORM PTO-1449 U.S. Dept. of Commerce Patent and Trademark Office LIST OF DISCLOSURES CITED BY APPLICANT (Use several sheets if necessary)	Atty Docket No. P1123R1D1C1	Serial No. Applicant Lowman et al.
	Filing Date	Group

U.S. PATENT DOCUMENTS

Examiner Initials	Document Number	Date	Name	Class	Subclass	Filing Date
	* 1	4,255,519	10.03.81	Terada et al.		
	* 2	4,275,149	23.06.81	Litman et al.		
	* 3	4,816,567	28.03.89	Cabilly et al.		
	* 4	5,534,617	09.07.96	Cunningham et al.		
	* 5	5,561,053	01.10.96	Crowley		
	* 6	5,622,700	22.04.97	Jardieu et al.		
	* 7	5,705,154	06.01.98	Dalie et al.		
	* 8	5,750,373	12.05.98	Garrard et al.		
	* 9	5,821,337	13.10.98	Carter et al.		
	**10	5,965,709	12.10.99	Presta et al.		
	**11	5,994,511	30.11.99	Lowman et al.		
	**12	6,037,453	14.03.00	Jardieu et al.		
	**13	6,054,297	25.04.00	Carter et al.		
	**14	6,329,509	11.12.01	Jardieu et al.		
	**15	6,407,213	18.06.02	Carter et al.		

FOREIGN PATENT DOCUMENTS

Examiner Initials	Document Number	Date	Country	Class	Subclass	Translation Yes	Translation No
	*16	239,400B1	03.08.94	EPO			
	*17	93/11161	10.06.93	PCT			
	18	WO 92/17207	15.10.92	PCT			
	*19	WO 93/04173	04.03.93	PCT			
	*20	WO 93/16185	19.08.93	PCT			
	21	WO 94/20533	15.09.94	PCT			
	*22	WO 95/24481	14.09.95	PCT			
	*23	WO 97/06822	27.02.97	PCT			

OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

	*24	Alberts et al., "The Immune System" <u>Molecular Biology of The Cell</u> , 3d edition, New York and London: Garland Publishing, Inc., Chapter 23, pps. G-15 and 1232
	*25	Amit et al., "Three-Dimensional Structure of an Antigen-Antibody Complex at 2.8 A Resolution" <u>Science</u> 233:747-753 (Aug 1986)
	*26	Barbas III et al., "In Vitro Evolution of a Neutralizing Human Antibody to Human Immunodeficiency Virus Type 1 to Enhance Affinity and Broaden Strain Cross-Reactivity." <u>Proc. Natl. Acad. Sci. USA</u> 91(9):3809-3813 (Apr 26, 1994)
	*27	Brennan et al., "Preparation of bispecific antibodies by chemical recombination of monoclonal immunoglobulin G ₁ fragments" <u>Science</u> 229:81-83 (July 1985)
	*28	Cacia et al., "Isomerization of an aspartic acid residue in the complementarity-determining regions of a recombinant antibody to human IgE: identification and effect on binding affinity" <u>Biochemistry</u> 35(6):1897-1903 (Feb 13, 1996)

Examiner

Date Considered

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449		U.S. Dept. of Commerce Patent and Trademark Office		Atty Docket No. P1123R1D1C1	Serial No.
LIST OF DISCLOSURES CITED BY APPLICANT (Use several sheets if necessary)				Applicant Lowman et al.	
				Filing Date	Group
OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)					
*29	Carter et al., "High Level Escherichia coli Expression and Production of a Bivalent Humanized Antibody Fragment." <u>Bio/Technology</u> 10(2):163-167 (Feb 1992)				
*30	Carter et al., "Humanization of an Anti-p185HER2 Antibody For Human Cancer Therapy" <u>Proc. Natl. Acad. Sci. USA</u> 89:4285-4289 (May 1992)				
*31	Champe et al., "Monoclonal antibodies that block the activity of leukocyte function-associated antigen 1 recognize three discrete epitopes in the inserted domain of CD11a" <u>Journal of Biological Chemistry</u> 270:1388-1394 (1995)				
*32	Chothia and Lesk, "Canonical Structures for the Hypervariable Regions of Immunoglobulins" <u>J. Mol. Biol</u> 196:901-917 (1987)				
*33	Chothia et al., "Domain Association in Immunoglobulin Molecules. The Packing of Variable Domains" <u>Journal of Molecular Biology</u> 186:651-663 (1985)				
*34	Chothia, C. et al., "Conformations of immunoglobulin hypervariable regions" <u>Nature</u> 342(6252):877-883 (1989)				
*35	Clackson et al., "Making Antibody Fragments Using Phage Display Libraries" <u>Nature</u> 352:624-628 (1991)				
*36	Co et al., "Humanized antibodies for antiviral therapy" <u>Proc. Natl. Acad. Sci. USA</u> 88:2869-2873 (April 1991)				
*37	Cunningham et al., "Production of an Atrial Natriuretic Peptide Variant that is Specific for Type A Receptor" <u>EMBO Journal</u> 13(11):2508-2515 (1994)				
*38	Geiger and Clarke, "Deamidation, isomerization, and racemization at asparaginy and aspartyl residues in peptides. Succinimide-linked reactions that contribute to protein degradation" <u>Journal of Biological Chemistry</u> 262(2):785-794 (Jan 15, 1987)				
*39	Goding, J.W., "Conjugation of antibodies with fluorochromes: modifications to the standard methods" <u>Journal of Immunological Methods</u> 13(3-4):215-226 (1976)				
*40	Hakimi et al., "The α subunit of the human IgE receptor (FcERI) is sufficient for high affinity IgE binding" <u>Journal of Biological Chemistry</u> 265(36):22079-22081 (1990)				
*41	Hawkins et al., "Selection of Phage Antibodies by Binding Affinity Mimicking Affinity Maturation" <u>J. Mol. Biol.</u> 226:889-896 (1992)				
*42	Herbert et al. <u>Dictionary of Immunology</u> , 3rd edition, Blackwell Scientific Publications pps. 77 (1985)				
*43	Holliger et al., "'Diabodies': Small Bivalent and Bispecific Antibody Fragments." <u>Proc. Natl. Acad. Sci. USA</u> 90:6444-6448 (Jul 1993)				
*44	Jones et al., "Replacing the Complementarity-Determining Regions in a Human Antibody with Those From a Mouse." <u>Nature</u> 321:522-525 (May 29, 1986)				
*45	Kabat et al. <u>Sequences of Proteins of Immunological Interest</u> , Bethesda, MD:National Institute of Health (1987)				
*46	Kabat <u>Sequences of Proteins of Immunological Interest</u> (Fourth Ed.), 4th edition pps. 41-42, 167-168 (1987)				
*47	Kabat <u>Sequences of Proteins of Immunological Interest</u> (pgs. 662-663, 671-672, 680-681, 697, 701-702, 710, 719-720, 2275-2276), 5th edition'1 (1991)				
*48	Kettleborough et al., "Humanization of a Mouse Monoclonal Antibody by CDR-grafting: the Importance of Framework Residues on Loop Conformation" <u>Protein Engineering</u> 4(7):773-783 (1991)				
Examiner				Date Considered	
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				Filing Date	Group
OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)					
	*49	Kohler and Milstein., "Continuous Cultures of Fused Cells Secreting Antibody of Predefined Specificity." <u>Nature</u> 256:495-497 (August 7, 1975)			
	*50	Konig et al., "Chemical and Biological Properties of Porcine Secretin and Secretin Analogues Modified in Positions 3 and 4" <u>Gastroenterology</u> 72:797-800 (1977)			
	*51	Kunkel et al., "Efficient site-directed mutagenesis using uracil-containing DNA" <u>Methods in Enzymology</u> 204:125-139 (1991)			
	*52	Lowe et al., "Allergen-induced Histamine Release in Rat Mast Cells Transfected with the α Subunits of Fc ϵ RI" <u>J. Immunological Methods</u> 184:113-122 (1995)			
	*53	Lowenson and Clarke, "Identification of isoaspartyl-containing sequences in peptides and proteins that are unusually poor substrates for the class II protein carboxyl methyltransferase" <u>Journal of Biological Chemistry</u> 265(6):3106-3110 (Feb 25, 1990)			
	*54	Lowman and Wells, "Affinity Maturation of Human Growth Hormone by Monovalent Phage Display" <u>J. Mol. Biol.</u> 234:564-578 (1993)			
	*55	Lowman et al., "Selecting High-Affinity Binding Proteins by Monovalent Phage Display" <u>Biochemistry</u> 30(45):10832-10838 (1991)			
	*56	Marks et al., "By-Passing Immunization: Building High Affinity Human Antibodies by Chain Shuffling" <u>Bio/Technology</u> 10:779-783 (1992)			
	*57	Marks et al., "By-Passing Immunization: Human Antibodies From V-gene Libraries Displayed On Phage" <u>J. Mol. Biol.</u> 222:581-597 (1991)			
	*58	McCafferty et al., "Phage antibodies: filamentous phage displaying antibody variable domains" <u>Nature</u> 348:552-554 (1990)			
	59	Metzger and Kinet, "How Antibodies Work: Focus on Fc Receptors" <u>FASEB J</u> 2(1):3-11 (January 1988)			
	*60	Morimoto et al., "Single-step purification of F(ab') ₂ fragments of mouse monoclonal antibodies (immunoglobulins G1) by hydrophobic interaction high performance liquid chromatography using TSKgel Phenyl-5PW" <u>Journal of Biochemical and Biophysical Methods</u> 24:107-117 (1992)			
	*61	Morrison et al., "Chimeric Human Antibody Molecules: Mouse Antigen-Binding Domains with Human Constant Region Domains" <u>Proc. Natl. Acad. Sci. USA</u> 81:6851-6855 (November 1984)			
	*62	Novotny et al., "Structural invariants of antigen binding: comparison of immunoglobulin V _L -V _H and V _L -V _L domain dimers" <u>Proc. Natl. Acad. Sci. USA</u> 82(14):4592-4596 (Jul 1985)			
	*63	Oliyai and Borchardt, "Chemical pathways of peptide degradation. IV. Pathways, kinetics, and mechanism of degradation of an aspartyl residue in a model hexapeptide" <u>Pharmaceutical Research</u> 10(1):95-102 (Jan 1993)			
	*64	Pluckthun., "Antibodies From Escherichia coli." <u>The Pharmacology of Monoclonal Antibodies: Handbook of Experimental Pharmacology</u> , Rosenberg and Moore, eds., Berlin:Springer-Verlag, Chapter 11, Vol. 113:269-315 (1994)			
	*65	Presta et al., "Humanization of an Antibody Directed Against IgE" <u>J. Immunol.</u> 151(5):2623-2632 (September 1, 1993)			
	*66	Presta, L., "Antibody Engineering" <u>Curr. Op. Struct. Biol.</u> 2:593-596 (1992)			
	*67	Riechmann et al., "Reshaping Human Antibodies for Therapy" <u>Nature</u> 332:323-327 (Mar 24, 1988)			
	*68	Routledge et al., "A Humanized Monovalent CD3 Antibody which Can Activate Homologous Complement" <u>European Journal of Immunology</u> 21:2717-2725 (1991)			
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OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)					
	*69	Shearman et al., "Construction, Expression and Characterization of Humanized Antibodies Directed Against the Human α/β T Cell Receptor" <u>J. Immunol.</u> 147(12):4366-4373 (December 15, 1991)			
	*70	Shields et al., "Inhibition of Allergic Reactions with Antibodies to IgE" <u>International Archives of Allergy and Immunology</u> 107(1-3):308-312 (May 1995)			
	*71	Sims et al., "A Humanized CD18 Antibody Can Block Function Without Cell Destruction" <u>The Journal of Immunology</u> 151(4):2296-2308 (Aug 1993)			
	*72	Suresh et al., "Bispecific Monoclonal Antibodies from Hybrid Hybridomas" <u>Methods in Enzymology</u> 121:210-228 (1986)			
	*73	Tempest et al., "Reshaping a Human Monoclonal Antibody to Inhibit Human Respiratory Syncytial Virus Infection In Vivo" <u>Bio/Technology</u> 9:266-271 (March 1991)			
	*74	Tutt et al., "Trispecific F(ab') ₃ Derivatives That Use Cooperative Signaling Via the TCR/CD3 Complex and CD2 to Activate and Redirect Resting Cytotoxic T Cells" <u>J. Immunol.</u> 147(1):60-69 (1991)			
	*75	Verhoeyen et al., "Reshaping Human Antibodies: Grafting an Antilysozyme Activity" <u>Science</u> 239:1534-1536 (Mar 25, 1988)			
	*76	Waterhouse et al., "Combinatorial infection and in vivo recombination: a strategy for making large phage antibody repertoires" <u>Nucleic Acids Research</u> 21:2265-2266 (1993)			
	*77	Yang et al., "CDR walking mutagenesis for the affinity maturation of a potent human anti-HIV-1 antibody into the picomolar range" <u>Journal of Molecular Biology</u> 254(3):392-403 (Dec 1, 1995)			
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